

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

To re Application of: Dennis M. TREU, et al.) Confirmation No: 4019
Application No.: 10/807,907)
Filed: March 23, 2004) Art Unit: 3761
) Examiner: Tatyana Zalukaeva

For: MECHANISM FOR MECHANICALLY BALANCING
FLOWS OF FLUIDS IN A BLOOD TREATMENT

United States Patent and Trademark Office
Customer Service Window, Mail Stop Restriction
Randolph Building
401 Dulany Street
Alexandria, Virginia 22314

RESPONSE TO RESTRICTION REQUIREMENT

Sir:

In response to the Restriction Requirement mailed October 12, 2006 in connection with the above-identified matter, the invention identified as Species A is hereby elected for examination on the merits. Applicants makes this election without traverse.

Applicants, of course, reserve the right to file one or more divisional applications covering the subject matter of the non-elected claims and inventions. Examination on the merits is kindly requested.

IN THE CLAIMS:

1. (original) A fluid balancing system for use in a renal replacement therapy procedure that takes in an ingoing fluid and outputs an outgoing fluid as part of said procedure, the ingoing and outgoing fluids being required to be maintained in a balanced relationship, the system comprising: a volumetric chamber assembly; a first flow assembly communicating with the volumetric chamber assembly and configured to supply a volume of the outgoing fluid and a volume of the ingoing fluid into the volumetric chamber assembly; a second flow assembly communicating with the volumetric chamber assembly for discharging a volume of the outgoing fluid and a volume of the ingoing fluid from the volumetric chamber assembly; and a synchronization unit configured to mechanically couple and thereby drive the first and second flow assemblies to effect a concurrent discharge of the outgoing fluid and ingoing fluid from the volumetric chamber assembly in volumetric balance with a concurrent supply of outgoing fluid and ingoing fluid into the volumetric chamber assembly.

2. (original) A system according to claim 1 wherein the volumetric chamber assembly is configured to be selectively placed in operative association with the first and second flow assemblies for use and selectively removed from operative association with the first and second flow assemblies after use.

3. (original) A system according to claim 1 wherein the volumetric chamber assembly includes at least one chamber including an interior wall dividing the chamber into a first compartment to retain a volume of outgoing fluid and a second compartment to retain a volume of ingoing fluid, the interior wall responding to differential fluid pressure to discharge the ingoing fluid from the second compartment as the outgoing fluid is conveyed into the first compartment, and vice versa.

4. (original) A system for volumetrically balancing the supply of ingoing fluid to, and the withdrawal of outgoing fluid from, a blood treatment process, comprising: a first chamber and a second chamber, each including an interior wall dividing the respective chamber into a first compartment to retain a volume of outgoing fluid and a second compartment to retain a volume of ingoing fluid, the interior wall responding to differential fluid pressure to displace outgoing fluid

from the first compartment as ingoing fluid is conveyed into the second compartment and vice versa, a first flow control assembly communicating with a source of outgoing fluid and the first compartments of the first and second chambers, a second flow control assembly communicating with a source of ingoing fluid and the second compartment of the first and second chambers, and a synchronization unit mechanically driving first and second flow control assemblies and operable in a first cycle, during which the first and second flow control assemblies convey a volume of outgoing fluid into the first compartment of the first chamber to displace a volume of ingoing fluid from the second compartment of the first chamber, while conveying ingoing fluid into the second compartment of the second chamber to displace a volume of outgoing fluid from the first compartment of the second chamber, the synchronization unit also being operable in a second cycle, during which the first and second flow control assemblies are driven to convey a volume of ingoing fluid into the second compartment of the first chamber to displace a volume of outgoing fluid from the first compartment of the first chamber, while conveying a volume of outgoing fluid into the first compartment of the second chamber to displace a volume of ingoing fluid from the second compartment of the second chamber, the synchronization unit operating during the first and second cycles to achieve a predetermined volumetric balance between outgoing fluid and ingoing fluid conveyed through the first and second chambers.

5. (original) A system for volumetrically balancing the supply of ingoing fluid supplied to a blood treatment device with the withdrawal of outgoing fluid from the treatment device comprising a first chamber and a second chamber, each including an interior wall dividing the respective chamber into a first compartment to retain a volume of outgoing fluid and a second compartment to retain a volume of ingoing fluid, the interior wall responding to differential fluid pressure to displace outgoing fluid from the first compartment as ingoing fluid is conveyed into the second compartment and vice versa, a first flow control assembly communicating with a source of outgoing fluid and the first compartments of the first and second chambers, a second flow control assembly communicating with a source of ingoing fluid and the second compartment of the first and second chambers, and a synchronization unit coupled to first and second flow control assemblies being operable in a first cycle, during which the first and second flow control assemblies are commanded to convey a volume of outgoing fluid into the first compartment of the first chamber to displace a volume of ingoing fluid from the second compartment of the first

chamber, while conveying ingoing fluid into the second compartment of the second chamber to displace a volume of outgoing fluid from the first compartment of the second chamber, the synchronization unit also being operable in a second cycle, during which the first and second flow control assemblies are commanded to convey a volume of ingoing fluid into the second compartment of the first chamber to displace a volume of outgoing fluid from the first compartment of the first chamber, while conveying a volume of outgoing fluid into the first compartment of the second chamber to displace a volume of ingoing fluid from the second compartment of the second chamber, the synchronization unit operating during the first and second cycles to achieve a predetermined volumetric balance between outgoing fluid and ingoing fluid conveyed through the first and second chambers; wherein the synchronization unit includes a drive assembly jointly coupled to the first and second flow control assemblies.

6. (original) A system according to claim 5 wherein the drive assembly mechanically couples the first and second flow control assemblies together.

7. (original) A system for volumetrically balancing the supply of ingoing fluid to a blood treatment device with the withdrawal of outgoing fluid from the blood treatment device, comprising: a first chamber and a second chamber, each including an interior wall dividing the respective chamber into a first compartment to retain a volume of outgoing fluid and a second compartment to retain a volume of ingoing fluid, the interior wall responding to differential fluid pressure to displace outgoing fluid from the first compartment as ingoing fluid is conveyed into the second compartment and vice versa, a first flow control assembly communicating with a source of outgoing fluid and the first compartments of the first and second chambers, a second flow control assembly communicating with a source of ingoing fluid and the second compartment of the first and second chambers, and a synchronization unit coupled to first and second flow control assemblies being operable in a first cycle, during which the first and second flow control assemblies are commanded to convey a volume of outgoing fluid into the first compartment of the first chamber to displace a volume of ingoing fluid from the second compartment of the first chamber, while conveying ingoing fluid into the second compartment of the second chamber to displace a volume of outgoing fluid from the first compartment of the second chamber, the synchronization unit also being operable in a

second cycle, during which the first and second flow control assemblies are commanded to convey a volume of ingoing fluid into the second compartment of the first chamber to displace a volume of outgoing fluid from the first compartment of the first chamber, while conveying a volume of outgoing fluid into the first compartment of the second chamber to displace a volume of ingoing fluid from the second compartment of the second chamber, the synchronization unit operating during the first and second cycles to achieve a predetermined volumetric balance between outgoing fluid and ingoing fluid conveyed through the first and second chambers; wherein the first flow control assembly includes a outgoing fluid inlet passage communicating jointly with the first compartments of the first and second chambers, and a first peristaltic pump unit operatively associated with the outgoing fluid inlet passage, wherein the second flow control assembly includes a ingoing fluid inlet passage communication jointly with the second compartments of the first and second chambers, and a second peristaltic pump unit operatively associated with the ingoing fluid inlet passage, and wherein the synchronization unit includes a drive assembly jointly coupled to the first and second peristaltic pump units.

8. (original) A system according to claim 7 wherein the synchronization unit includes a member to meter flow in the outgoing fluid inlet passage in proportion to flow in the ingoing fluid inlet passage during operation of the first and second peristaltic pump units.

9. (original) A system according to claim 8 wherein the member reduces fluid flow in the outgoing fluid inlet passage in proportion to fluid flow in the ingoing fluid inlet passage.

10. (original) A system for volumetrically balancing the supply of ingoing fluid used by a blood treatment with the withdrawal of outgoing fluid from the blood treatment, the system comprising: a first chamber and a second chamber, each including an interior wall dividing the respective chamber into a first compartment to retain a volume of outgoing fluid and a second compartment to retain a volume of ingoing fluid, the interior wall responding to differential fluid pressure to displace outgoing fluid from the first compartment as ingoing fluid is conveyed into the second compartment and vice versa, a first flow control assembly communicating with a source of outgoing fluid and the first compartments of the first and

second chambers, a second flow control assembly communicating with a source of ingoing fluid and the second compartment of the first and second chambers, and a synchronization unit coupled to first and second flow control assemblies being operable in a first cycle, during which the first and second flow control assemblies are commanded to convey a volume of outgoing fluid into the first compartment of the first chamber to displace a volume of ingoing fluid from the second compartment of the first chamber, while conveying ingoing fluid into the second compartment of the second chamber to displace a volume of outgoing fluid from the first compartment of the second chamber, the synchronization unit also being operable in a second cycle, during which the first and second flow control assemblies are commanded to convey a volume of ingoing fluid into the second compartment of the first chamber to displace a volume of outgoing fluid from the first compartment of the first chamber, while conveying a volume of outgoing fluid into the first compartment of the second chamber to displace a volume of ingoing fluid from the second compartment of the second chamber, the synchronization unit operating during the first and second cycles to achieve a predetermined volumetric balance between outgoing fluid and ingoing fluid conveyed through the first and second chambers; wherein the first flow control assembly includes a first inlet valve assembly controlling flow of outgoing fluid into the first compartments of the first and second chambers, and a first outlet valve assembly controlling flow of ingoing fluid from the second compartments of the first and second chambers, wherein the second flow control assembly includes a second inlet valve assembly controlling flow of ingoing fluid into the second compartments of the first and second chambers, and a second outlet valve assembly controlling flow of outgoing fluid from the first compartments of the first and second chambers, and wherein the synchronization unit includes a drive assembly jointly coupled to the first inlet valve assembly, the first outlet valve assembly, the second inlet valve assembly, and the second outlet valve assembly.

11. (original) A system according to claim 10 wherein the drive assembly mechanically links the first inlet valve assembly, the first outlet valve assembly, the second inlet valve assembly, and the second outlet valve assembly together.

12. (original) A system according to claim 10 wherein the first flow control assembly

includes a first pump to convey outgoing fluid to the first inlet valve assembly, and wherein the synchronization unit couples the drive assembly to the first pump.

13. (original) A system according to claim 12 wherein the drive assembly is mechanically linked to the first pump.

14. (original) A system according to claim 12 wherein the drive assembly ratiometrically links the first pump to the first inlet valve assembly, the first outlet valve assembly, the second inlet valve assembly, and the second outlet valve assembly.

15. (original) A system according to claim 10 wherein the second flow control assembly includes a second pump to convey ingoing fluid to the second inlet valve assembly, and wherein the synchronization unit couples the drive assembly to the second pump.

16. (original) A system according to claim 15 wherein the common drive assembly is mechanically linked to the second pump.

17. (original) A system according to claim 15 wherein the common drive assembly ratiometrically links the second pump to the first inlet valve assembly, the first outlet valve assembly, the second inlet valve assembly, and the second outlet valve assembly.

18. (original) A system according to claim 10 wherein the first flow control assembly includes a first pump to convey outgoing fluid to the first inlet valve assembly, wherein the second flow control assembly includes a second pump to convey ingoing fluid to the second inlet valve assembly, and wherein the synchronization unit couples the drive assembly to the first pump and the second pump.

19. (original) A system according to claim 18 wherein the drive assembly is mechanically linked to the first pump and the second pump.

20. (original) A system according to claim 18 wherein the common drive assembly ratiometrically links the first pump and second pump to the first inlet valve assembly, the first outlet valve assembly, the second inlet valve assembly, and the second outlet valve assembly.

21. (original) A blood treatment system, comprising a fluid circuit with a chamber including an interior wall dividing the chamber into a first compartment to retain a volume of a first fluid and a second compartment to retain a volume of a second fluid, the interior wall responding to differential fluid pressure to discharge the second fluid from the second compartment as the first fluid is conveyed into the first compartment, the first and second fluids being ingoing and outgoing fluids used in and/or arising from a blood treatment process; a flow control assembly comprising an inlet valve controlling flow of the first fluid into the first compartment, an outlet valve controlling flow of the second fluid from the second compartment, and a pump to convey the first fluid from a source into the first compartment through the inlet valve, and a synchronization unit coupled to the flow control assembly to volumetrically balance flow of the first fluid into the first compartment and discharge of the second fluid from the second compartment, the synchronization unit including a drive assembly that mechanically links together the inlet valve, the outlet valve, and the pump.

22. (original) A system according to claim 21 wherein the drive assembly ratiometrically links the inlet valve and the outlet valve to the pump, whereby changes in pump speed proportionally changes operation of the inlet valve and outlet valve.

23. (original) A system according to claim 21 wherein the pump includes a peristaltic pump having a drive motor.

24. (original) A fluid balancing system for use in a fluid processing procedure during which outgoing and ingoing fluids relating to a blood treatment are generated, the system comprising: volumetric chamber assembly; a first flow assembly communicating with the volumetric chamber assembly for supplying a volume of the outgoing fluid and a volume of the ingoing fluid into the volumetric chamber assembly; a second flow assembly communicating with the volumetric chamber assembly for discharging a volume of the outgoing fluid and a volume of the ingoing fluid from the volumetric chamber assembly; and a synchronization unit driving the first and second flow assemblies causing concurrent discharge of the outgoing fluid and ingoing fluid from the volumetric chamber assembly in volumeiric balance with a concurrent supply of outgoing fluid and ingoing fluid into the

volumetric chamber assembly.

25. (original) A system as in claim 24, wherein: said first and second flow assemblies include valves controlling flow into and out of said volumetric chamber assembly; and said valves are operated by said synchronization unit.

26. (original) A system as in claim 25, wherein: said first and second flow assemblies include pumps also operated by said synchronization unit.

27. (original) A system as in claim 26, wherein said pumps and said valves are mechanically coupled and driven by a common drive to achieve synchronization thereof.

28. (original) A system as in claim 24, wherein: said first and second flow assemblies include pumps also operated by said synchronization unit.

29. (original) A fluid balancing system for use in a blood treatment with ingoing fluids consumed by a blood treatment and outgoing fluids generated by said blood treatment in which the ingoing and outgoing fluids need to be balanced in quantity, the system comprising: a volumetric chamber assembly, a first flow assembly communicating with the volumetric chamber assembly for supplying a volume of the outgoing fluid and a volume of the ingoing fluid into the volumetric chamber assembly, a second flow assembly communicating with the volumetric chamber assembly for discharging a volume of the outgoing fluid and a volume of the ingoing fluid from the volumetric chamber assembly, and a synchronization unit configured to mechanically couple and thereby drive the first and second flow assemblies to effect a concurrent discharge of the outgoing fluid and ingoing fluid from the volumetric chamber assembly in volumetric balance with a concurrent supply of outgoing fluid and ingoing fluid into the volumetric chamber assembly; wherein the volumetric chamber assembly is configured to be selectively placed in operative association with the first and second flow assemblies for use and selectively removed from operative association with the first and second flow assemblies after use.

30. (original) A fluid balancing system for use with a patient treatment process in which an outgoing fluid is removed from a blood treatment process and an ingoing fluid is supplied to the blood treatment process, comprising: at least one first disposable volumetric chamber to receive said outgoing fluid and eject it into an outgoing fluid line; at least one second disposable volumetric chamber connected to eject said ingoing fluid into an ingoing fluid line; a synchronization unit including and operating at least one inlet valve, at least one outlet valve, at least one ingoing fluid pump and at least one outgoing fluid pump synchronously, said synchronization unit being operatively associated with said at least one first volumetric chamber and said at least one second disposable volumetric chamber such that outgoing fluid received by said first volumetric chamber displaces ingoing fluid in said second volumetric chamber, thereby determining a rate at which said ingoing fluid is ejected from said second pumping section; said synchronization unit being configured such that ingoing fluid is delivered continuously during a blood treatment without halting to empty said at least one second disposable pumping chamber.

31. (original) A system as in claim 30, wherein: said at least one first volumetric chamber includes two first volumetric chambers and said at least one second volumetric chamber includes two second volumetric chambers; and said synchronization unit is configured to empty a first of said two first volumetric chambers while filling a second of said two first volumetric chambers.

32. (original) A system as in claim 31, wherein said synchronization unit is configured to drive said at least one inlet valve and said at least one outlet valve in a synchronous fashion such that said first of said two first volumetric chambers presses directly against a first of said two second volumetric chambers as said first two volumetric chambers fill.

33. (original) A system as in claim 32, further comprising a common fixed volume that surrounds said first of said two first volumetric chambers and said first of said two second volumetric chambers such that first of said two first volumetric chambers press directly against said first of said two second volumetric chambers.

34. (original) A fluid balancing system for use with a patient treatment process in which an outgoing fluid and an ingoing fluid which are related to the treatment process are required to be in balance, the system comprising: first and second fluid circuits each with outgoing and ingoing fluid volumetric chambers connected hermetically to respective connectors for outgoing fluid withdrawal from a outgoing fluid source and outgoing fluid disposal and for ingoing fluid withdrawal from a supply; a mechanical synchronization unit including at least one pump; said first and second fluid circuit outgoing and ingoing fluid volumetric chambers each having flexible walls; valves controlling flow of fluid into and out of said volumetric chambers; said synchronization unit being configured to operate said valves such that during a first cycle, outgoing fluid filling said first fluid circuit outgoing volumetric chamber displaces ingoing fluid in said first fluid circuit ingoing fluid volumetric chamber as ingoing fluid filling said second fluid circuit ingoing fluid volumetric chamber displaces outgoing fluid in said second fluid circuit outgoing volumetric chamber and during a second cycle outgoing fluid filling said second fluid circuit outgoing volumetric chamber displaces ingoing fluid in said second fluid circuit ingoing fluid volumetric chamber as ingoing fluid filling said first fluid circuit ingoing fluid volumetric chamber displaces outgoing fluid in said first fluid circuit outgoing volumetric chamber.

35. (original) A system as in claim 34, wherein said first and second fluid circuits overlap such that two layers separate interiors of respective ones of said one of said ingoing fluid and outgoing volumetric chambers.

36. (original) A system as in claim 34, further comprising a chassis supporting said volumetric chambers.

37. (original) A fluid balancing system for use with a patient treatment process in which an outgoing fluid is removed and an ingoing fluid is supplied, comprising: a disposable fluid circuit including flexible wall portions defining at least one waste fluid chamber and at least one replacement fluid chamber; a drive mechanism including a pump engageable with said fluid circuit such that waste fluid may be pumped into said at least one waste fluid chamber; said drive mechanism operating valves synchronously such that replacement fluid is extracted

from said at least one replacement fluid chamber in equal volume increments as said at least one waste fluid chamber is filled; said drive mechanism being configurable to engage said disposable fluid circuit and reconfigurable for conducting said patient treatment process.

38. (original) A system as in claim 37, wherein said drive mechanism includes a pair of recesses that enclose said at least one waste fluid chamber and said at least one replacement fluid chamber to define a fixed volume when said drive mechanism is configured to engage said disposable fluid circuit, whereby fluid filling said waste fluid chamber directly displaces fluid in said replacement fluid chamber.

39. (original) A fluid balancing system for use with a patient treatment process in which an outgoing fluid ingoing fluid relating to the treatment process are required to be in balance, the system comprising: a fluid circuit with volumetric chambers; a blood treatment device with a motor, pumps, and valves operatively associated with said fluid circuit and configured such that said pumps and valves are synchronously driven by said motor; said fluid circuit being removable from said blood treatment device.

40. (original) A system as in claim 39, wherein said blood treatment device includes cams to drive said valves.

41. (original) A system as in claim 39, wherein said at least one pump includes a replacement fluid pump and a waste fluid pump, each mechanically coupled to synchronize them with said at least one valve.

42. (original) A system as in claim 39, wherein said at least one valve includes inlet and outlet valves respective to said at least one of said volumetric chambers and inlet and outlet valves respective to said at least another of said volumetric chambers.

43. (original) A system as in claim 39, wherein said blood treatment device includes a cam mechanism to operate said at least one valve.

44. (original) A fluid balancing system for use with a patient treatment process in which a outgoing fluid and ingoing fluid, relating to a treatment process, are required to be in

balance during a treatment of a patient, the system comprising: a fluid circuit with volumetric chambers; a blood treatment device with a motor, at least one pump, and at least one valve operatively associated with said fluid circuit and configured such that said at least one pump and said at least one valve are synchronously driven by said motor such that said outgoing fluid is moved into at least one of said volumetric chambers displacing ingoing fluid in at least another of said volumetric chambers; said fluid circuit being removable from said blood treatment device.

45. (original) A system as in claim 44, wherein said blood treatment device includes a cam mechanism to operate said respective inlet and outlet valves.

46. (original) A system for volumetrically balancing the supply of ingoing fluid to a blood treatment process with the withdrawal of outgoing fluid from the blood treatment process, the system comprising a first chamber and a second chamber, each including an interior wall dividing the respective chamber into a first compartment to retain a volume of outgoing fluid and a second compartment to retain a volume of ingoing fluid, the interior wall responding to differential fluid pressure to displace outgoing fluid from the first compartment as ingoing fluid is conveyed into the second compartment and vice versa, a first flow control assembly communicating with a source of outgoing fluid and the first compartments of the first and second chambers, a second flow control assembly communicating with a source of ingoing fluid and the second compartment of the first and second chambers, and a synchronization unit coupled to first and second flow control assemblies being operable in a first cycle, during which the first and second flow control assemblies are commanded to convey a volume of outgoing fluid into the first compartment of the first chamber to displace a volume of ingoing fluid from the second compartment of the first chamber, while conveying ingoing fluid into the second compartment of the second chamber to displace a volume of outgoing fluid from the first compartment of the second chamber, the synchronization unit also being operable in a second cycle, during which the first and second flow control assemblies are commanded to convey a volume of ingoing fluid into the second compartment of the first chamber to displace a volume of outgoing fluid from the first compartment of the first chamber, while conveying a volume of outgoing fluid into the first compartment of the

second chamber to displace a volume of ingoing fluid from the second compartment of the second chamber, the synchronization unit operating during the first and second cycles to achieve a predetermined volumetric balance between outgoing fluid and ingoing fluid conveyed through the first and second chambers; wherein the synchronization unit is operable in a transition cycle between the first and second cycles, and wherein, during the transition cycle, the synchronization unit operates the first and second flow control assemblies to prevent flow of both outgoing and ingoing fluids into the respective first and second compartments.

47. (original) A fluid balancing system for use with a patient treatment process in which an outgoing fluid is generated and an ingoing fluid is consumed, comprising: a fluid circuit with volumetric chambers; a blood treatment device with a ingoing fluid pump, a outgoing fluid pump, and a motor; said blood treatment machine including valves operatively associated with said fluid circuit; said blood treatment machine being configured such that said ingoing fluid pump and said outgoing fluid pump are mechanically interlocked, such that said outgoing fluid is moved into at least one of said volumetric chambers displacing ingoing fluid in at least another of said volumetric chambers, and driven synchronously by said motor; said fluid circuit being removable from said blood treatment device.

48. (new) A system as in claim 1, further comprising a base machine with a recess, wherein the volumetric chamber assembly includes a chamber that includes a flexible portion that fits into the recess.

49 (new) A system as in claim 1 further comprising a base machine with a recess, wherein the volumetric chamber assembly includes a chamber that includes a flexible portion that fits into the recess, the shape and size of the recess determining the internal volume of the chamber..

REMARKS

The Office Action required the election of one of two identified species, namely, Species A, associated with claims 1-38 or Species B associated with claims 39-43. Applicants have elected the Species A. Claims 1-38 read on this species.

Applicants have added new claims 48 and 49, which depend from claim 1. The new claims fall within the elected species.

The Commissioner is hereby authorized by this paper to charge any fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-3840. This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,



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